

# Breakout Area 1: X-Ray & X-Ray CT:

## What can be measured over time?

### Near-Term 1-3 Years

- **OA: Poor sensitivity to change of monitoring progression of JSW with X-ray is too imprecise to allow cost effective use in clinical trials. MRI may be more sensitive to change, but this has not been qualified sufficiently to revise current regulatory guidance.**
  - More sensitive and confident assessment of progression of cartilage loss with fewer patients and shorter study duration may accelerate drug development.
  - Lack of validation data
  - Academia, Pharma, FDA
- **Lung CA: Breathing movements during CT of a lung nodule potentially shifts the location of sections on serial examinations. Current solutions involve unfavorable tradeoffs.**
  - Improved accuracy of diagnosis and therapeutic response based on longitudinal change
  - ??
  - Key Players: Academia, Pharma, CT industry
- **Lung CA: Dimensional measurements of lung tumors do not accurately measure the malignant portion, complicating measurement of response to therapy. CT density, especially following iv contrast, may differentiate the malignant region better. Understanding “truth” is the goal.**
  - Improved accuracy of diagnosis and therapeutic response
  - Validation data
  - Pharma, CT industry, and NIH

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## 1. *BMD and bone geometry results vary between different CT scanners*

- ❑ **Impact of Success:** ability to pool data from different centers and studies; ability to accommodate midstream scanner changes in longitudinal studies
- ❑ **Technical Barriers:** Changes to CT hardware and software necessary; lack of adequate phantoms
- ❑ **Key Players:** CT vendors, QCT vendors, Phantom manufacturers; NIST

## 2. *No truth standard exists for bone geometry*

- ❑ **Impact of Success:** Tool for development and evaluation of bone endpoints and software to measure those endpoints
- ❑ **Technical Barriers:** Difficult data to collect, lack of agreement on method to determine truth, definition of endosteal boundary
- ❑ **Key Players:** Academics, NIH, NIST

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1. *Lack of method to assess accuracy and stability of microCT scanner performance*
  - ❑ **Impact of Success:** confidence in microCT results, increased likelihood of making correct conclusions from data
  - ❑ **Technical Barriers:** Difficulty to manufacturer an appropriate anthropomorphic phantom
  - ❑ **Key Players:** microCT manufacturers, phantom manufacturers, academics, NIST
2. *No standardization of computational methods for 3D stereological analysis of bone microCT images*
  - ❑ **Impact of Success:** Measurement definitions are standardized and measurements from different sources are comparable
  - ❑ **Technical Barriers:** Limited research and investigation of different approaches
  - ❑ **Key Players:** Academics, microCT vendors, NIST